

---

# Chapter 5

## How the Biosolids Risk Assessment Results Were Used in the Part 503 Rule

**T**he results of the biosolids risk assessments were used to establish Part 503 pollutant limits. Other elements of the Part 503 rule were established to provide a more comprehensive and protective regulation (see Figure 1 in Chapter 1), for example:

- To be consistent with data used in the various risk assessments (e.g., an assumption used in the risk assessment calculation was a 10-meter buffer zone between land-applied biosolids and surface waters. Hence, a Part 503 management practice was placed in the rule that requires a 10-meter buffer zone from surface waters for land application).
- To ensure that the information needed to meet pollutant limits would be available (e.g., some Part 503 monitoring and recordkeeping requirements pertain to operating conditions and emissions from biosolids incinerators; others ensure that biosolids meet cumulative pollutant loading rate limits for land application).
- To provide protection for areas not addressed by the risk assessments (e.g., the Part 503 operational standard for pathogen reduction and vector attraction reduction, and many of the Part 503 management practices).

This chapter first summarizes the biosolids risk assessments, as discussed throughout this document. It then briefly presents key aspects of the Part 503 rule as they relate to the risk assessments, focusing on how the biosolids risk assessment results were used to establish the Part 503 pollutant limits. Some of the Part 503 requirements that were not based on the risk assessments also are discussed. For more information on the Part 503 rule, see EPA's *A Plain English Guide to the EPA Part 503 Biosolids Rule* (U.S. EPA, 1994).

# Synopsis of the Biosolids Risk Assessments

## History of the Risk Assessment Process

As discussed in Chapter 2, the process of establishing pollutant limits was extensive. In 1984, EPA produced a preliminary list of 200 pollutants potentially found in biosolids for which a risk assessment might be appropriate. Experts reviewed this list and narrowed it down to approximately 50 pollutants to be considered for regulation, based on toxicity and exposure data. After initial evaluations of these 50 pollutants (i.e., a hazard index screening, see Chapter 2, Tables 2 and 3), EPA determined that 31 of these pollutants should undergo a detailed biosolids risk assessment. From 1986 to 1988, the initial, detailed risk assessments for these 31 pollutants were conducted for the proposed Part 503 rule. After receiving numerous peer review and public comments on the proposed rule published in 1989, a second round of risk assessments was conducted with the assistance of biosolids experts from outside the Agency from 1990 to 1992 for the final Part 503 rule. These revised risk assessments incorporated numerous changes based on the review comments (as discussed in Chapters 2 and 3). The results of the revised risk assessments were the basis for setting pollutant limits in the final Part 503 rule.

## Defining Exposure Pathways and Highly Exposed Individuals

The basic approach for assessing risks from biosolids involved:

- Identifying appropriate pollutants to be evaluated (as discussed above and in Chapter 2).
- Defining the highly exposed individuals (HEIs) for relevant exposure pathways (e.g., a child ingesting biosolids or an adult eating crops grown on biosolids-amended soils) for pollutants of concern.
- Identifying or developing appropriate parameters (e.g., variables for toxicity, dietary consumption, and food production) that could be used in algorithms (equations) to calculate pollutant limits (as discussed in Chapter 4).
- Assessing risks to HEIs in relevant pathways of exposure. (HEIs and the biosolids exposure pathways used are listed in Chapter 2, Tables 6, 7, and 8).

This approach was used for all types of risks—to people, animals, or plants—associated with inorganic and organic pollutants. Defining realistic HEIs (i.e., highly exposed individuals that really could exist in a population) was one of several key challenges of the risk assessments. The approach used early on in the biosolids risk assessment process (i.e., for the proposed rule) was the use of a most exposed individual (MEI). Reviewers of this approach commented that the definition of the MEI involved so many conservative assumptions that it was highly improbable that such an individual could exist. In risk assessment terminology, the MEI represented bounding estimates. Further evaluation of the MEI showed that his or her exposure would be higher than the 100th percentile (i.e., higher than 100 percent of the most exposed population). Thus, for the revised risk assessment for the final Part 503 rule, EPA used the concept of an HEI rather than an MEI to define individuals that because of their circumstances were at the high end of the exposure distribution, but still had a finite possibility of existing (i.e., did not exceed the 100th percentile for exposure). The HEI was defined by a combination of conservative (high-end) and average (mid-range) assumptions, as recommended in EPA's 1992

risk assessment guidance (Habicht, 1992, see Chapter 3). Nevertheless, the HEIs remain conservative representations of the exposed population (as shown in the example risk assessment for cadmium in Chapter 4).

## Choosing Parameters To Identify Pollutant Limits

### Risks to People and Animals

Different parameters were used to calculate pollutant limits for different types of risks (or, different values were assigned to the same parameter). For example:

- For human health risks, the fundamental health-based parameters used were the risk reference dose (RfD) for noncarcinogens and the cancer potency value ( $q_1^*$ ) for carcinogenic pollutants (see Chapter 2). These parameters define intakes of pollutants that, based on an array of considerations, are considered acceptable. Both RfDs and  $q_1^*$ s include significant safety factors, which contribute to the conservatism of the Part 503 pollutant limits for protection of humans in relevant exposure pathways.
- For risks to domestic animals and wildlife, the primary protective health parameter used was the threshold pollutant intake (TPI) of the most sensitive or most exposed species. This parameter was the calculated maximum pollutant intake in the diet associated with no toxic effects. Risks to animals also included factors for bioavailability and bioaccumulation to account for the uptake of pollutants in soil by earthworms and earthworm predators as well as a bio-concentration factor in fish for the surface-water pathway.
- For risks to soil organisms, a pollutant concentration in soil considered to have no adverse effects (called the RLC) was developed and used as the protective health parameter.

### Risks to Plants

For risks to plants, a series of comprehensive approaches was used. In conjunction with other experts, EPA conducted an in-depth review of the scientific literature on plant uptake of metals (including over 270 journal articles) and field study data on plant metal concentrations. For such risks:

- EPA first analyzed different levels of vegetative growth reduction (e.g., from 8 to 50 percent reduction in growth) associated with various leaf concentrations of metals and corresponding soil metal loadings. Maximum loading rates were identified that would not exceed an acceptable phytotoxicity threshold.
- Next, EPA analyzed data to identify plant tissue levels of metals associated with first detectable yield reductions in sensitive plant species as an alternate way to develop phytotoxicity thresholds and pollutant limits. Plant response slopes for the uptake of metals were then calculated from the thresholds for sensitive species to identify metals application rates that would not exceed the thresholds.
- As described in Chapter 3 (Section N-3) and Chapter 4 (Box 13), EPA then selected the more restrictive of the two phytotoxicity limits (as determined by the approaches noted above) as the pollutant limit for phytotoxicity in the risk assessment.
- In reality, no loading rates for potentially phytotoxic metals were identified in any of the field studies analyzed that would exceed the established phytotoxicity threshold concentrations. Thus, extra protection was provided by the conservatively established pollutant limits for phytotoxicity.

## Choosing a Pollutant Limit

As described in Chapter 4, a number of different exposure pathways were evaluated for each pollutant. The pathway with the lowest pollutant limit was identified as

the “limiting pathway,” and this lowest value was used as the pollutant limit in the risk assessment for each pollutant. The most limiting pathways and the risk assessment pollutant limits are listed in Tables 11, 13, and 14 (Chapter 4) for land application, surface disposal, and incineration.

## Evaluating Inorganic and Organic Pollutants

Both inorganic and organic pollutants were evaluated in the biosolids risk assessments. For these two types of pollutants, different parameters and algorithms were used in the risk assessment calculations to reflect the fact that many organic pollutants degrade in the environment. Organic pollutants for land application and surface disposal were not regulated in the Part 503 rule, however, for the reasons discussed in Chapter 3. For incineration, organic pollutants were regulated through a THC (or CO) operational standard (discussed later in this chapter).

## Using Conservative Assumptions

For many of the parameters and methodologies used, a number of associated assumptions and policy decisions were made. For example, assumptions were made regarding plant uptake of pollutants (the UC parameter) and the fraction of food produced on biosolids-amended land (the FC parameter), as discussed in Chapter 4. In many cases, the assumptions and policy decisions made were conservative to account for uncertainties that remained in the carefully assembled data sets. Three examples are:

- The assumption that a certain minimal level of plant uptake of pollutants occurs, even when available data showed no increased plant uptake.
- The assumption that home gardeners produce and consume 59 percent of their annual yearly leafy vegetable consumption, while a more reasonable assumption might be the production and consumption of 10 percent of their leafy vegetables.
- The selection of the most exposed or most sensitive species as the HEI for protection of ecological species.

A number of key assumptions were changed (i.e., made less conservative) after EPA received comments indicating that the proposed Part 503 pollutant limits were based on unrealistically conservative assumptions. Thus the revised risk assessments were calculated combining assumptions having conservative high-end (low) probabilities of occurrence with assumptions having mid-range (average) probabilities of occurrence. Using this approach, the 95th to 98th percentiles of the subset of the population comprised of individuals who might be adversely effected by pollutants in biosolids were protected by the final Part 503 rule (such as the subsistence home gardener described in Chapter 4, who might be consuming food produced in soils where the cumulative pollutant loadings were already at their maximum permitted level). The revised risk assessments resulted in a final Part 503 rule that was both highly protective and more realistic and less stringent than the initial proposed rule.

# The Biosolids Risk Assessments and the Part 503 Rule

The pollutant limits identified in the biosolids risk assessments were used either directly or with modification to establish the pollutant limits in the Part 503 rule, as discussed below.

## Pollutant Limits for Land Application

### Four Types

The four types of pollutant limits established for land application in the final Part 503 rule are shown in Table 16 and described below:

- **Cumulative pollutant loading rates (CPLRs):** One type, called the CPLR, was taken directly from the biosolids risk assessment results (Table 2 in Part 503). CPLRs apply to biosolids with pollutant concentrations in excess of Part 503's Table 3 values (see also Table 16 in this guidance document) that are applied to land in bulk. Part 503 requires that accurate records be kept of the amounts of pollutants applied to a site from biosolids subject to CPLRs. Attainment of the CPLR for a pollutant means that no more CPLR biosolids can be applied to that site. Even at the CPLR, however, the pollutant loading is protective of public health and the environment. Other biosolids that meet the pollutant concentration limits, described below, can still be land applied safely, even on a site where the CPLR has already been reached.

**Table 16**  
**Risk Assessment Results and Part 503 Pollutant Limits for Land Application**

Pollutant		Table 2, Part 503 Rule	Table 4, Part 503 Rule	Table 1, Part 503 Rule	Table 3, Part 503 Rule
	Risk Assessment Results (RP <sub>C</sub> , kg-pollutant/ ha, DW)	CPLR Limit <sup>a</sup> (kg-pollutant/ ha, DW)	APLR Limit <sup>b</sup> (kg-pollutant/ ha/yr, DW)	Ceiling Concentration Limit <sup>c</sup> (mg-pollutant/ kg- biosolids, DW)	Pollutant Concentration Limit (mg-pollutant/ kg- biosolids, DW) (monthly average)
Arsenic	41	41	2.0	75	41
Cadmium	39	39	2.0	85	39
Chromium <sup>d</sup>					
Copper	1,500	1,500	75	4,300	1,500
Lead	300	300	15	840	300
Mercury	17	17	0.85	57	17
Molybdenum <sup>e</sup>	18			75	
Nickel	420	420	21	420	420
Selenium	100	100	5.0	100	100 <sup>f</sup>
Zinc	2,800	2,800	140	7,500	2,800

<sup>a</sup>CPLR limits were taken directly from the risk assessment results and pertain only to biosolids applied in bulk.

<sup>b</sup>APLR limits were derived from the CPLR limits (see text) and pertain only to biosolids sold or given away in bags or other containers.

<sup>c</sup>Ceiling concentration limits are either the 99th-percentile concentrations in the National Sewage Sludge Survey or the risk assessment pollutant limits, whichever were least stringent (see text and Box 15).

<sup>d</sup>Chromium limits are not shown because they most likely will be deleted from the rule (see also Chapter 3).

<sup>e</sup>Some molybdenum limits are not shown because they are under reconsideration and are presently not part of the rule (except for the ceiling concentration limit, which remains in effect).

<sup>f</sup>A change in the pollutant concentration limit for selenium is expected based on a recent court decision (see also Chapter 3).

- **Annual pollutant loading rates (APLRs):** A second type of Part 503 biosolids pollutant limit is the APLR. The APLRs, which apply only to biosolids that are sold or given away in a bag or other container, identify the maximum amounts of pollutants in biosolids that can be applied to a site in any one year. APLR biosolids, like CPLR biosolids, contain pollutant levels in excess of the Part 503 Table 3 pollutant concentration limits. The APLRs were derived by dividing the CPLRs by 20, reflecting an assumed 20 applications annually at the same rate to a given site. APLRs were established because imposing CPLRs was not practical, given the difficulty in establishing a chain of control from preparer to applicator of bagged or containerized biosolids. Part 503 requires that APLR biosolids must be accompanied with labeling information to ensure that they are used properly and that the APLR is not exceeded.

EPA concluded that 20 years is a reasonable conservative assumption for APLRs because biosolids sold or given away in a bag or other container will probably be applied to a lawn, home garden, or public contact site and therefore probably will not be applied longer than 20 years at the same site, particularly not 20 consecutive years.

- **Ceiling concentration limits:** A third type of pollutant limit for land application, called the ceiling concentration limit, identifies biosolids with the maximum allowable concentrations of pollutants that can be land applied. These limits were established in Part 503 as minimum-quality limits to prohibit the lowest quality (highest metal content) biosolids from being land applied. Biosolids with high metals concentrations are a concern because metals at high levels might behave more like metal salts, which are taken up by plants much more readily than metals at the low levels typically found in biosolids (see Chapter 3). Including ceiling limits also may bolster public confidence in the land application of biosolids. The ceiling concentration limits are either the 99th-percentile concentration for each pollutant, as defined by the National Sewage Sludge Survey (NSSS), or the pollutant limits identified in the risk assessment, whichever is the least stringent (see Box 15, this chapter, and Section N-6 of Chapter 3).
- **Pollutant concentration limits:** The last and most stringent type of Part 503 limit is called the pollutant concentration limit. These risk-based limits were derived by assuming a 1,000-mt/ha application of biosolids in which the cumulative pollutant loading rates would be met but not exceeded. The pollutant concentration limits define no-adverse-effect biosolids that can be land applied safely without the applicator keeping track of cumulative pollutant loadings, as is required for biosolids meeting CPLRs discussed above (see also the description of pollutant concentration limits in Chapter 3). The pollutant concentration limits were derived from the pollutant limits identified in the risk assessments. (Prior to a recent court decision [see Section Q, Chapter 3], the 99th-percentile NSSS concentrations were imposed as pollutant concentration limits when they were lower than the risk assessment limits.)

If biosolids can be shown to meet the pollutant concentration limits listed in Table 3 of Part 503, as well as certain Part 503 pathogen and vector control requirements (discussed later in this chapter), these biosolids (sometimes called exceptional quality [EQ] biosolids) can be land applied as freely as other fertilizers and soil conditioners without also having to show they meet the Part 503 management practices and general requirements. Recordkeeping, monitoring, and reporting requirements would still be in effect, but the burden of these stipulations would be considerably diminished without the need to track pollutant loadings. Numerous field studies supported this approach; research results showed no adverse effects from applying biosolids with the low levels of pollutants defined by the pollutant concentration limits.

As discussed above, the derivation of ceiling concentration limits was based on prohibiting the use of lower quality (high metal) biosolids, including pollutants that would behave more like metal salts. At the same time, the use of pollutant concentration limits encourages the use of high-quality biosolids. The decision to use ceiling concentration and pollutant concentration limits, whether arising from risk-based calculations or other data, was an EPA policy decision. This decision helped implement EPA's comprehensive risk management policy that incorporates the goals of promoting the use of high-quality biosolids and maintaining the existing quality of land-applied biosolids. The policy decision to use these types of limits also added further conservatism to the Part 503 rule. Box 15 provides an example of how Part 503 ceiling concentration limits and pollutant concentration limits were derived.

To summarize, all land-applied biosolids must meet the Part 503 ceiling concentration limits. Biosolids also must meet either (1) the Part 503 pollutant concentration limits, or (2) the Part 503 CPLRs or APLRs, as discussed above. Thus, EPA used both risk-based limits and policy decisions to develop the land application pollutant limits in the Part 503 rule.

### Box 15

#### How Part 503 Ceiling and Pollutant Concentration Limits Were Derived

Example for copper:

- The **pollutant limit** (RP<sub>C</sub>) identified in the biosolids land application risk assessment for copper was 1,500 kg of copper per hectare (see Chapters 3 and 4).
- To convert the pollutant limit to a **pollutant concentration limit**, EPA used the assumptions that biosolids would be applied to a site for 100 years at a rate of 10 metric tons per year (a total of 1,000 metric tons per hectare of biosolids application), which represents 1,500 mg of copper per kg of biosolids:

$$\begin{aligned} \text{Pollutant concentration limit} &= \frac{1,500 \text{ kg of copper per hectare (risk assessment limit)}}{100 (\text{site life, yrs}) \cdot 10 (\text{annual application rate, mt-biosolids DW/ha} \cdot \text{yr}) \cdot 0.001} \\ &= 1,500 \text{ mg of copper per kg of biosolids} \end{aligned}$$

(Note: 0.001 is a conversion factor)

Including pollutant concentration limits encourages the use of superior quality biosolids, because if the pollutant concentration limits and certain Part 503 pathogen and vector requirements are met, the biosolids can be used as freely as any other type of fertilizer or soil conditioner.

- To derive the **ceiling concentration limit**, the 99th-percentile pollutant concentration in the National Sewage Sludge Survey (NSSS) was identified. For copper, this was 4,300 mg of copper per kg of biosolids. The results of the risk assessment and the NSSS survey were then compared and the least stringent (i.e., higher) of the risk assessment or NSSS number (4,300 mg/kg) was selected as the ceiling concentration limit; this limit prevents biosolids with high concentrations of pollutants from being land applied.

	Risk Assessment Pollutant Limit	NSSS 99th %	Part 503 Ceiling Concentration Limit	Part 503 Pollutant Concentration Limit
Copper	1,500	4,300	4,300	1,500 <sup>a</sup>

<sup>a</sup>All numbers are mg of pollutant/kg of biosolids, DW. The Part 503 pollutant concentration limits are monthly averages.

## Pollutant Limits for Surface Disposal

EPA used either the 99th-percentile pollutant concentrations from the NSSS or the pollutant limits identified in the risk assessment, whichever were more stringent, as the pollutant limits for unlined surface disposal units in the Part 503 rule. The Agency determined that risks from surface disposal sites with liners and leachate collection systems were negligible; thus, the Part 503 approach for surface disposal includes pollutant limits only for biosolids disposed at surface disposal sites without liners and leachate collection systems.

Surface disposal sites often comprise a number of cells, or units, that accept biosolids and may or may not be active. Part 503 pollutant limits for active units without liners and leachate collection systems differ depending on the distance between the unit boundary and the surface disposal site boundary. The risk assessment proved to be sensitive to the assumption of distance to the property line for unit boundaries 150 feet or less from the surface disposal site property line, and thus the Part 503 limits reflect these distance differences. The Agency made a decision to manage risks by tailoring limits for active biosolids units within surface disposal sites based on property line distance, rather than requiring all surface-disposed biosolids to meet unnecessarily restrictive limits based on worst-case property line distances. The Agency also determined that risks from the surface disposal of biosolids through the surface-water pathway could be managed much more efficiently through management practices (discussed later in this chapter) that prevent biosolids from entering surface water rather than through substantially more stringent pollutant limits.

Some inorganic pollutants (copper, lead, and mercury) were not regulated in Part 503 for surface disposal because they met one of three criteria that EPA used to delete pollutants from biosolids regulation (i.e., they were not expected to exceed the pollutant limits identified in the risk assessment, based on NSSS data; see “Deletion of Pollutants” in Chapter 3).

## Pollutant Limits for Incineration

Four of the seven inorganic pollutant limits in Part 503 for biosolids incineration were derived using information from the biosolids risk assessment (i.e., risk-specific concentrations for arsenic, cadmium, chromium, and nickel), as described in Chapter 4. Because of the limited number of incinerators affected, the Agency chose to use site-specific pollutant limit calculations. This approach allows risks to be managed in accordance with incinerator performance (see Box 16).

Beryllium and mercury pollutant limits were incorporated by reference to the National Emission Standards for Hazardous Air Pollutants (NESHAPS) for these pollutants, which are health-based standards. The pollutant limit for lead was based on a percentage of the National Ambient Air Quality Standard (NAAQS), rather than a risk-specific concentration for lead. EPA chose this approach for beryllium, mercury, and lead to be consistent with existing air quality regulations. EPA concluded that meeting the NESHAPS, or the pollutant limit calculated for lead using the NAAQS factor and site-specific data, protects public health from reasonably anticipated adverse effects of these pollutants in biosolids.

## Other Elements of the Part 503 Rule

In addition to pollutant limits, other elements of the Part 503 rule include general requirements; operational standards; management practices; and frequency of monitoring, recordkeeping, and reporting requirements (see also Figure 1 in Chapter 1). Several of these additional elements are discussed below to highlight their relationship to the risk-based pollutant limits.

### Box 16

#### Equations Used To Calculate Part 503 Pollutant Limits for Incineration

For arsenic, cadmium, chromium, and nickel:<sup>a</sup>

$$\text{Part 503 pollutant limit} = \frac{RSC \cdot 86,400}{DF \cdot (1-CE) \cdot SF}$$

For lead:<sup>a</sup>

$$\text{Part 503 pollutant limit} = \frac{0.1 \cdot NAAQS \cdot 86,400}{DF \cdot (1-CE) \cdot SF}$$

Where:

RSC = Risk specific concentration (micrograms per cubic meter)

NAAQS = National Ambient Air Quality Standard for lead (micrograms per cubic meter)

*Site-Specific Factors:*

DF = Dispersion factor, site-specific (micrograms per cubic meter per gram per second)

CE = Biosolids incinerator control efficiency for arsenic, cadmium, chromium, lead, or nickel; site-specific (hundredths)

SF = Biosolids feed rate, site-specific (metric tons per day), dry-weight basis

Hypothetical example calculation for arsenic:

Parameter	Value	Units
RSC	0.023	µg/m <sup>3</sup>
Conversion factor	86,400	sec/day
<i>Site-Specific Factors</i>		
DF	3.4	µg/m <sup>3</sup> /g/sec
CE	0.975	hundredths
SF	12.86	mt/day, DW

$$\text{Part 503 pollutant limit} = \frac{RSC \times 86,400}{DF \times (1-CE) \times SF} = \frac{0.023 \times 86,400}{3.4 \times (1-0.975) \times 12.86} = 1,818 \text{ mg/kg of arsenic}$$

<sup>a</sup>See the Part 503 rule for specific requirements for these calculations (e.g., stack height, performance tests)

## Operational Standards

In most cases, EPA determined that risk-based pollutant limits could be calculated to achieve the goal of protecting public health and the environment from reasonably anticipated adverse effects of pollutants in biosolids, given the state of the science of risk assessment. In three cases, however, risk assessment methodologies were not sufficiently developed to provide a reasonable estimate of risk. Thus, EPA determined that the most appropriate way for the Agency to manage risks in these instances was to use operational standards rather than risk-based pollutant limits. The Clean Water Act specifically provides for alternatives to numeric limits for biosolids use or disposal in certain circumstances:

If...it is not feasible to prescribe or enforce a numeric limitation for a pollutant...the Administrator may instead promulgate a design, equipment, management practice or *operational standard* [emphasis added]...which in the Administrator's judgment is adequate to protect public health and the environment from any reasonably anticipated adverse effect of such pollutant. [Clean Water Act, Section 405(d)(3)]

The Part 503 rule contains three operational standards. One standard regulates pathogen reduction in biosolids; the second addresses vector attraction reduction in biosolids; and the third covers total hydrocarbon (THC) limits in incinerator emissions. Each of these operational standards is discussed below.

### The Operational Standards for Pathogen and Vector Attraction Reduction

EPA determined that a risk assessment approach for pathogen and vector attraction reduction in biosolids was not yet sufficiently developed to establish risk-based limits. Thus, EPA chose to manage risks from pathogens (and risks from vectors spreading those pathogens) through operational standards. The Agency concluded that the best way to meet the objective of protecting public health and the environment was to have biosolids meet certain technology-based requirements for minimizing or eliminating pathogen densities and reducing vector attraction. These requirements can be met either directly by taking measurements or by using certain approved processes known to reduce pathogens and vector attraction to levels judged reasonably safe by EPA.

With respect to pathogens, two levels of control can be met: Class A, which allows the use of biosolids with fewer restrictions because pathogen densities are below detectable levels; and Class B, which, because pathogen densities are reduced but are still detectable, is associated with a number of site and harvesting restrictions that allow sufficient time for environmental degradation of pathogens prior to contact. Domestic septage is required to meet certain pH requirements and site restrictions similar to those for Class B biosolids. More information on the Part 503 pathogen and vector attraction reduction requirements can be found in EPA's **A Plain English Guide to the EPA Part 503 Biosolids Rule** (U.S. EPA, 1994) and **Control of Pathogens and Vector Attraction in Sewage Sludge** (U.S. EPA, 1992d).

### The Operational Standard for THC

Based on comments received on the proposed Part 503 rule, the Agency decided to replace its proposed risk-based THC concentration approach with an operational, technology-based standard. EPA set the operational standard for THC in emitted incinerator off-gases at 100 ppm based on testing at three incinerators. After evaluating the aggregate impact analysis, which indicated minimal health effects from current biosolids incinerator practices, along with site data on THC

emissions, EPA concluded that this operational standard would protect public health from any reasonable anticipated adverse effects. As discussed in Chapters 2 and 4, EPA later included carbon monoxide (CO) monitoring (100-ppm limit) as an alternate, acceptable method of ensuring that the THC emissions operational standard would be met.

## **Management Practices**

In general, management practices in the Part 503 rule were stipulated for the three use or disposal practices (land application, surface disposal, or incineration) for one of three reasons:

- To protect public health and the environment when specific pathways or end-points were not analyzed in the risk assessment (e.g., threatened or endangered species requirements for land application and surface disposal of biosolids).
- To embody assumptions that were incorporated into the risk assessment and thus need to be met in practice to ensure that risk levels are not exceeded (e.g., a 10-meter buffer zone around bodies of surface water for land-applied biosolids).
- To require that information be provided where risk levels might be exceeded if biosolids were not handled properly (e.g., labeling requirement for bagged or containerized biosolids for land application).

Thus, management practices were included in Part 503 to (1) constrain risks when actual risks were not evaluated, (2) support risk modeling assumptions, or (3) ensure proper handling of biosolids. Where risks were determined to be negligible (as discussed below), the Agency considered the appropriate strategy was to refrain from subjecting the biosolids to management practice requirements. The management practice requirements for the three use or disposal practices are listed in Table 17 and are discussed below.

### **Management Practices for Land Application**

As shown in Table 17, management practices are used in conjunction with pollutant limits and other elements of the Part 503 rule to govern the land application of biosolids. Management practices are used to protect threatened or endangered species; restrict land application on flooded, frozen, or snow-covered land; impose a 10-meter buffer between land-applied biosolids and U.S. waters; require agronomic rates pertaining to nitrogen; and require labeling for bagged or containerized biosolids, unless certain conditions, discussed below, are met.

Biosolids that meet the Part 503 pollutant concentration limits and certain Part 503 pathogen and vector attraction reduction requirements are not subject to the general requirements and management practices (listed in Table 17) for land application because the Agency has determined that the risks associated with the land application of these biosolids are negligible. Also, bagged biosolids applied to a lawn or home garden are not subject to management practice requirements other than labeling because the Agency determined that it is unlikely that large amounts of bagged biosolids would be applied to a lawn or home garden multiple times. The risks associated with this scenario are thus considered negligible.

### **Management Practices for Surface Disposal**

EPA established the Part 503 management practices listed in Table 17 for surface disposal of biosolids when risks to human health and the environment were not addressed by the risk assessment, and to ensure protection of surface water, air quality, ground water, and human health from pollutants that may be present in biosolids at surface disposal sites.

**Table 17**  
**Part 503 Management Practices**

Management Practice	Reason Included in Rule
<b>Land Application<sup>a</sup></b>	
Protection of threatened or endangered species	Consistency with federal regulation (50 CFR 17.11 and 17.12)
Restriction of land application on flooded, frozen, or snow-covered land	Prevents biosolids from entering surface waters and wetlands
Ten-meter buffer for U.S. waters	Protects waters of the U.S.; helps ensure risk is no greater than that calculated in the biosolids risk assessment, which assumed a 10-m buffer zone from surface waters
Agronomic application rate limit for nitrogen	Protects ground water from nitrate contamination
Labeling requirements for bagged or containerized biosolids	Helps ensure that applicators use proper application rates, which ensure that pollutant limits are met
<b>Surface Disposal</b>	
Protection of threatened or endangered species	Consistency with federal regulation (50 CFR 17.11 and 17.12)
Prohibition against restriction of base flood flow	Protects area's flooding capacity; also protects surface water and public health from the release of pollutants in biosolids if a base flood occurs
Geological stability requirements	Protects the structural integrity of the surface disposal site and prevents the release of leachate (which may contain pollutants in biosolids) from the site
Protection of wetlands	Protects wetlands from possible contamination when biosolids are placed in a surface disposal site
Collection of runoff	Prevents runoff from a surface disposal site (which may contain pollutants in biosolids) from being released into the environment
Collection of leachate	Prevents leachate from a surface disposal site from being released into the environment
Methane gas limit	Ensures explosive conditions do not exist at site
Restriction on crop production	If no crop production, prevents pollutants in biosolids at surface disposal sites from being consumed by humans/animals; if crop production allowed, <sup>b</sup> helps ensure levels of pollutants taken up by crops do not negatively affect the food chain
Restriction on grazing	If no grazing, prevents animals from ingesting pollutants in biosolids at surface disposal sites; if grazing allowed, <sup>b</sup> helps ensure that levels of pollutants taken up by crops do not negatively affect the food chain
Restriction of public access	Minimizes public contact with pollutants that may be present in biosolids at surface disposal sites
Protection of ground water	Protects ground water from nitrate contamination
<b>Incineration</b>	
Measurement of THC or CO in stack gases	Protects air quality by ensuring proper incinerator operation
Measurement of oxygen in stack gases	
Measurement of moisture content in stack gases	
Measurement of combustion temperature	
Measurement of operating parameters for pollution control devices	
Protection of threatened and endangered species	Consistency with federal regulation (50 CFR 17.11 and 17.12)

<sup>a</sup>In addition to these management practices, site and harvesting restrictions are included in the pathogen and vector attraction reduction requirements to protect human/animal health for crop consumption by ensuring that pathogen concentrations in crops are at or below levels identified in the risk assessment.

<sup>b</sup>Crop production or grazing are allowed at surface disposal sites only if the site owner/operator can demonstrate that human health and the environment are protected from reasonably anticipated adverse effects of pollutants in biosolids.

## Management Practices for Incineration

The Part 503 rule requires that management practices relating to the measurement of key parameters must be followed at biosolids incinerators. The required measurements are necessary to show that the incinerator is operating properly and to ensure that pollutant limits are being met. They are also a necessary enforcement tool. The management practices for incineration are listed in Table 17.

## Part 503 Monitoring, Recordkeeping, and Reporting Requirements

Monitoring, recordkeeping, and reporting are necessary to ensure that risks are properly managed. Further, these requirements form the basis for enforcing the regulation. Without the ability to enforce the rule, the Agency cannot be sure that the risk levels specified in the rule will be met. The Agency determined, however, that the frequency of monitoring, the types of records and reports maintained, and report submission requirements could vary, given the variable risks posed by different practices, quantities of biosolids produced, and classifications of POTWs.

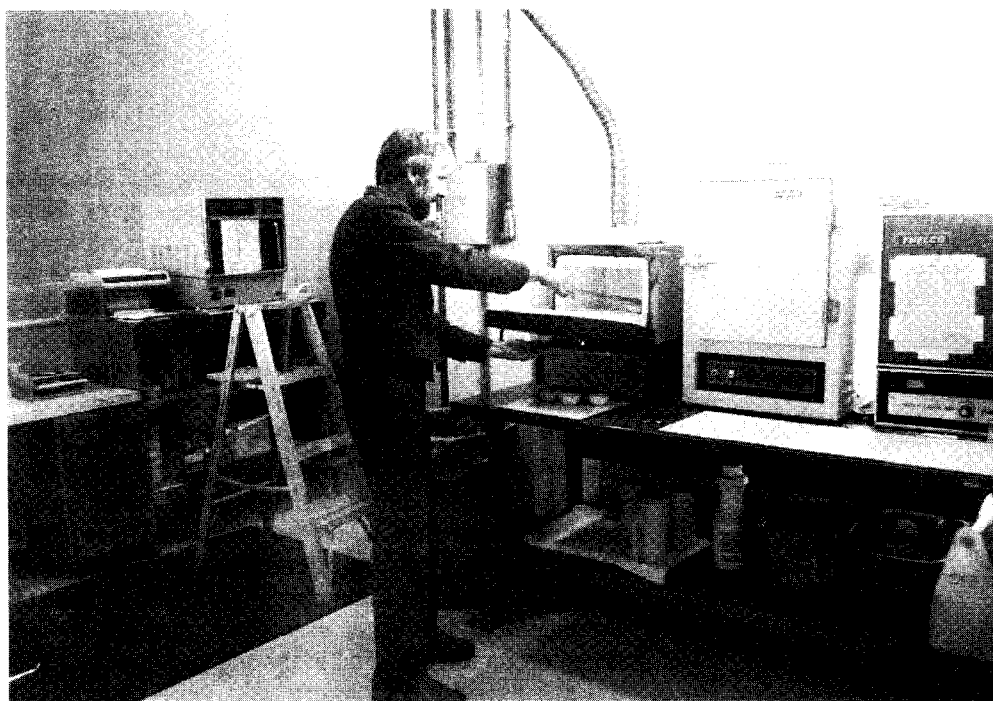
For further information on all of the elements of the Part 503 rule, see EPA's *A Plain English Guide to the EPA Part 503 Biosolids Rule* (U.S. EPA, 1994). For the Part 503 rule's approach for regulating domestic septage (i.e., less burdensome requirements than for biosolids at certain types of sites), see EPA's *Domestic Septage Regulatory Guidance: A Guide to the EPA Part 503 Rule* (U.S. EPA, 1993).

## General Summary

EPA conducted three comprehensive risk assessments for pollutants in biosolids that are land applied, surface disposed, or incinerated. The risk assessments evaluated risks to human health through relevant exposure pathways for each of the three use or disposal practices, as well as ecological risks (to animals and plants) for land application and surface disposal. Using appropriate parameters that represented relevant data and assumptions, the risk assessments quantitatively identified allowable concentrations or application rates of pollutants in biosolids that are used or disposed that protect human health and the environment from reasonably anticipated adverse effects.

The results of the risk assessments were used as a basis for establishing the final Part 503 pollutant limits, aided in some cases by EPA policy decisions. The risk assessments involved a number of conservative assumptions and data management decisions that provided protective yet realistic Part 503 requirements. Additional protective measures also were included in the rule (e.g., operational standards, management practices, and monitoring and recordkeeping requirements) to address areas not included in the risk assessment or to support assumptions made in the risk assessment. Where risks were negligible, less burdensome requirements were allowed, such as exempting "clean" (or "exceptional quality") biosolids from management practices and general requirements for land application and setting alternate requirements for domestic septage.

Using the best available data, the biosolids risk assessments identified limits for pollutants in biosolids that protect public health and the environment. The Part 503 rule, based on the risk assessments, sets forth conservative pollutant limits and other requirements without being overly restrictive, while allowing the beneficial and safe use of biosolids.



Ongoing monitoring ensures that biosolids are being used in accordance with Part 503 requirements that were established based on the biosolids risk assessments. The top photograph shows a technician collecting a representative composite sample of a dried biosolids product. The bottom photograph shows this sample being dry ashed in preparation for chemical analysis.